4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2012-N-0377]

Clinical Study Design and Performance of Hospital Glucose Sensors

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting entitled "Clinical Study Design and Performance of Hospital Glucose Sensors." The purpose of this public meeting is to discuss clinical study design considerations and performance metrics for innovative glucose sensors intended to be used in hospital point of care settings.

Date and Time: The public meeting will be held on June 25, 2012**,** from 8 a.m. to 5 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm. The public meeting will also be available to be viewed online via webcast.

Contact: Vicki Moyer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5626, Silver Spring, MD 20993, 301-796-6148, FAX: 301-847-8513, email: vicki.moyer@fda.hhs.gov.

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this meeting must register online by 4 p.m., June 15, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.66, rm. 4321, Silver Spring, MD 20993, 301-796-5661, email: susan.monahan@fda.hhs.gov, no later than June 15, 2012.

To register for the public meeting, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see Registration section of this document). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Web cast of the Public Meeting: This public meeting will also be Web cast. Persons interested in viewing the Web cast must register online by 4 p.m., June 15, 2012. Early registration is recommended because Web cast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after June 20, 2012. If you have never attended a Connect Pro

event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Requests for Oral Presentations: This public meeting includes a public comment session. During online registration you may indicate if you wish to speak and the proposed title for the public comment session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment. Following the close of registration, FDA will determine the amount of time allotted to each speaker and will select and notify participants by June 19, 2012. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Comments: FDA is holding this public meeting to obtain information on innovative kinds of hospital glucose sensors. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting electronic or written comments on all aspects of the meeting topics. The deadline for submitting comments related to this public meeting is July 23, 2012.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments

may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the meeting on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this meeting from the posted events list.).

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking input from the clinical community, academia, Government, industry, clinical laboratories, and other stakeholders regarding clinical validation studies and performance criteria for hospital glucose sensors. These types of devices are intended to be used at the patient bedside, and are different from currently available glucose sensors in that they are generally indwelling or inserted. Furthermore, they are often designed to collect continuous or near-continuous glucose concentrations for each patient.

These devices have the potential to benefit patient care but to date they are not widely available. This is due, in part, to the challenges in designing and studying these complex devices. One challenge is the study design itself; determining the types of patients to include and what data are needed to adequately validate performance is often difficult given the varied hospital

environment and patient populations. Once the study is complete, determining whether or not the results are sufficiently accurate and reliable for the proposed intended use(s) is equally challenging.

The purpose of this public meeting is to share information about the challenges in validating these kinds of hospital glucose sensors and solicit public input and discussion. The feedback may increase communication and collaboration within the stakeholder community, and, ultimately, help overcome some of the current challenges associated with designing clinical studies and generating clinical performance data for these devices.

The public meeting will include two sessions of the following topics: (1) The clinical studies and data needed to adequately validate the performance of these devices in the intended use population and (2) discussion of metrics that may be used to evaluate results to demonstrate a safe and effective device. Each session will include presentations from physicians, Government, and other experts in the field. Presentations will be followed by panel discussions of session topics and questions from the audience.

II. Topics for Discussion at the Public Meeting

The following questions represent the kinds of topics that will be discussed at the meeting. The final questions to be discussed at each session will be available the day of the meeting.

1. Who is the likely intended use population for these devices and how will they be used in patient management? For example, will they be used for general hospital, surgical, critically ill, pediatric patients, etc.? What are the study considerations for evaluating the devices in these different populations?

2. How does the intended use of the device affect the design of the clinical studies and the evaluation and adequacy of device performance? For example, are the accuracy needs for a device used to monitor trends over time different from the accuracy needs of one where the individual glucose results are used to replace discrete glucose measurements? Is greater accuracy needed when the device is used in certain populations? What metrics can be used to evaluate whether or not results from these devices are sufficiently accurate and reliable for the proposed intended use(s)?

3. What conditions, medications, or therapies have the potential to cause interference and require evaluation? What kinds of studies/models are appropriate to evaluate interference?

4. Differences in glucose concentrations may be observed when testing arterial and venous blood samples from the same patient. How can the potential differences in blood glucose concentrations be addressed when conducting the clinical studies?

Dated: May 15, 2012.

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Center for Devices and Radiological Health.

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